

## Efficacy of Topical Microfibrillar Collagen Mixed with Steroid Hormone and Morphine for Postoperative Pain Control during Lumbar Laminectomy: A Preliminary Report

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**Background:** Current inpatient management of postoperative pain in lumbar surgery includes the use of intramuscular opioid analgesics, nonsteroidal anti-inflammatory drugs, or patient-controlled analgesia; however, all types of medications are associated with side effects that can limit their usefulness in the inpatient setting.

**Methods:** In a well-conducted non-randomized prospective trial, 80 consecutive patients who underwent elective multilevel lumbar laminectomy surgery were identified. Two types of trials with different doses of steroids were used. Patients' preoperative medical records, pain scores, narcotics consumption, costs for the regimen, hospital stay, unwanted complications, and walking ability were evaluated postoperatively.

**Results:** Pain in patients after lumbar surgery can be dramatically controlled postoperatively. Seventy-eight patients (97.5%) were able to walk without support on the first postoperative day. Major side effects were found in 5 patients (6.2%).

**Conclusions:** This experience indicates that pain-control agents with epidural sustained-released preparation seem to be beneficial in early mobilization, are cost effective, and require lower analgesic consumption by patients. Similar pain control can be obtained with lower doses of methylprednisolone. In spite of its clinical attractiveness, improvements in the side effects of complications from epidural morphine and the combination of steroids and microfibrillar collagen have yet to be realized.

*(Chang Gung Med J 2002;25:81-8)*

**Key words:** epidural morphine, methylprednisolone, laminectomy, pain.

Pain after spinal surgery can be difficult to control. Patients often fear postoperative pain more than the risks of the operation itself.<sup>(1)</sup> Ineffective pain therapy in inpatients has been commonly reported.<sup>(2,3)</sup> Until recently, laminectomy was performed as a common surgical procedure for multilevel lumbar

spinal stenosis. Management of postoperative discomfort remains the critical issue in clinical practice. The popularity of patient-controlled analgesia (PCA) in use after lumbar surgery is based on the assumption that postoperative pain control is better with self-administration of opioids using small, repetitive,

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Received: Jul. 19, 2000; Accepted: Sep. 26, 2001

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concentration- maintained, on-demand intravenous doses than with timed (around-the-clock) or demanded intramuscular or oral application of an analgesic. However, the negative effects from PCA turned our focus to finding a more efficient method to try to minimize the pain from operations and the adverse effects from narcotics.<sup>(4)</sup> Since the report of Gibbons et al.<sup>(5)</sup> in 1995, many investigators<sup>(6-9)</sup> have demonstrated the efficacy of epidural use of morphine and steroids associated with local anesthesia during a lumbar operation for postoperative pain control. The purposes of this study were to thoroughly evaluate the effectiveness for postoperative wound pain control using an epidural pain-control regimen containing low doses of morphine and methylprednisolone, and to analyze the duration of pain subsidence, the cost, and the unwanted complications from the pain-control agents.

## METHODS

This study prospectively examined 80 patients who underwent lumbar laminectomy procedures performed by 1 physician from March 1998 to January 2000. All patients were admitted to Chang Gung Memorial Hospital, Taoyuan, Taiwan, to undergo operations for benign conditions of the lumbar spine, and informed consent was obtained from each. Exclusive criteria were sequestered disc herniation,

biomechanically unstable spine, or previous surgery at the treated level. Preoperative variables including age, sex, duration of symptoms, historical use of herbal drugs or acupuncture, and major diseases were thoroughly assessed. Pain scores (on a 4-point pain scale), narcotics consumption, costs for the regimen, hospital stay, unwanted complications, and walking ability of patients were evaluated postoperatively. Accordingly, we collected the subjects with major unwanted complications, and tried to evaluate the relationship between past history and adverse effects.

There were two separate trials in this study. After adjustment for baseline differences from the methylprednisolone used, 37 patients were enrolled in group A, and 43 patients were enrolled in group B (Table 1). Based on the 16% infection rate during the first trial, we adjusted the dose of methylprednisolone beginning in December 1998. In the first trial (Group A) of the study, absorbable microfibrillar collagen (Avitene, Davol Inc., Cranston, RI) was soaked in 80 mg of methylprednisolone (Solumedrol, Upjohn Co., Kalamazoo, MI) and 3 mg of preservative-free morphine with a thickness of about 0.5 cm on the dura surface to allow maximum absorption. During wound closure, the paravertebral muscles and subcutaneous tissues were injected with 20 ml 0.25% bupivacaine (Abbott Lab., North Chicago, IL) combined with 40 mg methylprednisolone. The second

**Table 1.** Clinical Information on 80 Patients with Epidural Pain-Controlled Regimen Application

Variable	Group A (N=37)	Group B (N=43)	<i>p</i>
Regimen constituent			
Epidural	Avitene (microfibrillar collagen) 80 mg methylprednisolone 3 mg morphine	Avitene 40 mg methylprednisolone 3 mg morphine	
Subcutaneous	20 cc, 0.25% bupivacaine 40 mg methylprednisolone	20 cc, 0.25% bupivacaine	
Age (year)	60.4 ± 8.7	61.9 ± 7.3	0.726
Gender (M:F)	16:21	18:25	>0.950
Major disease	12	18	NA
Herb/Acupuncture	9	13	NA
Walking without support (hr) (mean ± SD)	17.6 ± 4.7	17.2 ± 4.0	0.703
First voiding (hr) (mean ± SD)	2.61 ± 3.64	2.16 ± 3.42	0.573
LOS (day) (mean ± SD)	6.0 ± 5.5	5.0 ± 2.3	0.261

NA: non-applicable; Major disease: diabetes, hypertension, renal disease, heart failure, coagulopathy or lung disease; Herb/acupuncture: a history of treatment with herbal drugs and/or acupuncture; First voiding, duration to first self voiding after intraurethral catheter removed; LOS, length of stay.

**Table 2.** Frequency of Self-administered Narcotics (50 mg Meperidine Hydrochloride) Use in 63 Patients

Group	Frequency	Post-operative periods					Total patient's no.
		0-1 hr	1-8 hrs	8-24 hrs	1-3 days	>3 days	
A	1	4	15	1	1	0	21
	2	0	a,b,c,d,	d	a,c,	b*	4
	> 3	0	e	e	e (2),f (2)	e*(3), f*(2)	2
B	1	7	24	2	0	0	33
	2	0	g,h (2)	g	0	0	2
	> 3	0	0	0	i	i* (3)	1

a - e, represents individual patient; (n), frequency of narcotics injection during specific time periods; \*: deeply infected patients.

**Table 3.** Patient Number with Side Effects in Groups A and B

Side effect	Post-operative periods		
	3-8 hrs (A/B)	8-24 hrs (A/B)	over 24 hrs (A/B)
Respiration depression	2 (2/0)	0	0
Nausea	13 (4/9)	6 (2/4)	1*(0/1)
Vomiting	2 (1/1)	1* (0/1)	0
Ileus	4 (1/3)	1* (0/1)	0
Constipation	NA	NA	8 (3/5)
Urinary retention	NA	2 (1/1)	1* (0/1)
Wound dehiscence/swelling	0	0	3 (3/0)
Wound infection (superficial)	0	0	3 (3/0)
Wound infection (deep)	0	0	4 (3/1)
Skin itchiness	0	4 (1/3)	2* (0/2)
Clonus convulsion	1 (1/0)	1* (1/0)	0

A/B, number of patients in groups A and B; \*: patients with residual symptoms from previous time period.

trial (Group B) of the study used epidural microfibrillar collagen soaked with 40 mg methylprednisolone and 3 mg of preservative-free morphine associated with subcutaneous 20 ml of 0.25% bupivacaine for postoperative pain control.

All patients underwent a standard clinical evaluation, including history of systemic disease (history of hypertension, diabetes, cardiopulmonary disease, renal failure, and coagulation disease), physical examination, planar radiographic study, and magnetic resonance imaging (MRI) performed under general anesthesia. Anesthesia was induced in all patients with midazolam (up to 2 mg), propofol (1.5-2.0 mg/kg), and muscle relaxant. The patients' tracheas were intubated, and anesthesia was maintained with N<sub>2</sub>O/O<sub>2</sub> 70%/30% (nitrous oxide/oxygen), 3 ug/kg fentanyl, and isoflurane (at up to 1.5% end-tidal concentration). After induction of general anesthesia,

patients were placed in the knee-chest position on a laminectomy seat. A 10- to 12-cm midline skin incision was made under intraoperative fluoroscope localization. Subperiosteal dissection along the spinous process and lamina was made. Rongeurs and Kerrison were then used to remove the 2 to 3 levels of spinous process, lamina, hypertrophic facets, and ligamentum flavum. After the dura sac, exiting roots, and hemostasis were confirmed, microfibrillar collagen was contoured to loosely pack the laminectomy defect. Microfibrillar collagen was soaked in 80 mg (Group 1) or 40 mg (Group 2) of methylprednisolone (Solumedrol) and 3 mg of preservative-free morphine with a thickness of about 0.5 cm on the dura surface to allow maximum absorption. During wound closure, the paravertebral muscles and subcutaneous tissues were injected with 20 ml of 0.25% bupivacaine alone in patients of Group B or com-

bined with 40 mg methylpredisone in patients of Group A. The patient was then awakened and extubated. During the postoperative period, patients were prescribed oral nonsteroidal anti-inflammatory drugs and 50 mg meperidine hydrochloride intramuscularly every 6 hours as needed. The pain scores and nausea assessment were conducted by nursing staff or residents upon the patient's arrival in the post anesthesia care unit and at 30 minutes, 1 hour, and every 8 hours thereafter. For patients who were discharged, we assessed the wound condition at an average of 7.52 postoperative days in the outpatient clinic. To assure the effectiveness of the epidural pain-control regimen, pain evaluation focused on the area of the wound. In other words, during evaluation, complaints from the hip or leg pain were ignored, and to exclude possible effects from the anesthesia, side effects from the pain-control regimen were thoroughly evaluated 3 hours after surgery.

Time of first ambulation and first voiding were documented, as was narcotics consumption. The intraurethral catheter was routinely removed the next morning. Patients were encouraged to stand and walk when they were comfortable doing so. After surgery, the baseline pain score was assessed with the aid of the standard pain scale as follows: 0=no pain, 1=minimal or occasional pain not requiring medication, 2=mild pain controlled with non-narcotic analgesics, 3=moderate pain controlled with occasional narcotic analgesics, and 4=severe constant pain requiring regular narcotic analgesics.<sup>(10)</sup>

In pain scale, intramuscular narcotics consumption, respiratory patterns, nausea, itching, and ability to control voiding were evaluated. The cost of the pain-control regimen and length of stay were assessed. Independent *t*-test and chi-squared test were used to compare the effectiveness and unwanted side effects of the 2 trials. All results were considered statistically significant at  $p < 0.05$ .

## RESULT

Demographic data and clinical characteristics obtained from the 80 patients are summarized in Table 1, and total intramuscular narcotics consumption was noted in 63 patients (78.7%) as summarized in Table 2. The age at surgery ranged from 48 to 81 years (mean  $\pm$  SD, 60.8  $\pm$  7.56 years), and was slight-

ly female dominant. After the intraurethral catheter was removed the next morning, most patients had the ability to control voiding during 2.6-hour periods (1-22 hours). The average time for controlled voiding was 2.61  $\pm$  3.64 hours in group A and 2.16  $\pm$  3.42 hours in group B ( $t=0.567$ ,  $p=0.573$ ). Seventy-eight patients (97.5%) were able to walk without support at least for a short distance on the first postoperative day. The average time for encouraged ambulatory walking was 17.6 hours in group A and 17.2 hours in group B ( $t=0.383$ ,  $p=0.703$ ). There was no statistically significant difference in length of stay of the 2 groups (6.0  $\pm$  5.5 days in group A and 5.0  $\pm$  2.3 days in group B,  $p=0.261$ ). Twelve subjects in group A and 18 subjects in group B had a history of health problems with severe medical diseases; 22 patients (9 in group A and 13 in group B) reported a history of using herbal drugs and/or acupuncture treatment.

Twenty-one patients (26.2%) in group A and 33 patients (41.2%) in group B received 50 mg of meperidine hydrochloride once and most (50/54) within 8 hours (Table 2). Seven patients needed narcotics after 24 hours postoperatively (patients a, b, c, e, f, I, and 1 patient in group A). Among them, 4 (patients b, e, f, and i) were found to have deep infections (57.1%). The pain scale records of the 2 groups are illustrated in Fig. 1. Data were collected 1 hour, 8 hours, 24 hours, 3 days, and 7 days postoperatively. Average scores in group A were 2.69  $\pm$  0.62, 2.11  $\pm$  0.70, 1.47  $\pm$  0.81, 1.16  $\pm$  0.73, and 0.86  $\pm$  0.72, while in group B, scores were 2.79  $\pm$  0.67, 2.44  $\pm$  0.62, 1.95  $\pm$  0.78, 1.27  $\pm$  0.59 and 1.27  $\pm$  0.50 at the respective individual times. Although group A showed a better pain response, there were no statistical differences in postoperative 1-hour and 3-day time periods. Sixty-eight patients (85%) were essentially pain-free or with minimal wound pain under regular oral analgesics with no need for narcotics after 8 hours postoperatively. Seventy-three patients (91.2%) still felt the wound was painless at 7 days postoperatively, excluding the 3 patients with superficial and the 4 with deep infected wounds (Table 2).

Possible adverse events from the epidural and subcutaneous regimen are shown in Table 3. Nausea and vomiting occurred in 15 patients within 8 hours which decreased to 7 patients (8.7%) at 24 hours.

Only 1 patient complained of the nausea after 24 hours postoperatively. Urinary retention was a complaint of 2 patients who had delayed voiding 12 hours postoperatively, after the intraurethral catheter was removed. Respiratory depression was noticed in 2 patients within 8 hours postoperatively, and they were treated successfully with oxygen support. Abdominal disturbance (ileus) with poor peristalsis was noted in 4 patients (1 patient in group A and 3 in group B) within 24 hours, and constipation was recorded after 24 hours in 8 patients (10%). Skin itchiness was a complaint of 4 patients. All minor side effects were treated uneventfully and were resolved within 3 days postoperatively.

Major adverse effects occurred in 5 patients (1 with clonic convulsion and 4 with deep wound infections). One patient in group A suffered from back tightness and severe restlessness 3 hours postoperatively, then proceeded to clonic convulsions and respiratory failure at the neurosurgical ward, and was treated by emergent endotracheal tube insertion and medication. The incidence of infection was 16.2% (6 patients) in group A and 2.3% (1 patient) in group B. These consisted of superficial wound infections in 3 (3 in group A and none in group B) and deep infections in 4 (3 in group A and 1 in group B). These lesions were noted 3.6 ± 2.4 days (3 to 7 days) postoperatively. The pain was severe enough to reuse intramuscular narcotics 24 hours after surgery in all 4 deep infection cases (Table 2). The pathogen was *Staphylococcus aureus* in all 4 patients. The prognosis was uneventful after the patients were treated with surgical debridement and 14 days of parenteral antibiotics. Tracing the past history of 5 patients with major complications, 3 deep infection subjects (cases b, e, and i) reported herbal drug/acupuncture treatment within 3 months before surgery. The patient who suffered from postoperative clonic convulsions had a history of an allergic reaction to narcotic injections 3 years previous when she had undergone surgery for a hysterectomy.

The average costs of the epidural pain-control regimen and subcutaneous injection was about NT\$2,800 in group A (approximately US\$85) and about NT\$2,500 in group B.

## DISCUSSION

The pain model used in these 2 trials was based

on draft documents issued by several basic scientific studies reported in the anesthesia and surgical literature.<sup>(7,11-15)</sup> The objective of our research was not only to study the short-term effects of epidural regimens, but also to accurately assess the risk of this combination and the economic effect in our patients. Use of an epidural sustained-release pain-control regimen, containing morphine and methylprednisolone, may effectively reduce the postoperative wound pain in most patients, as reported by most studies in the relevant literature.<sup>(6,8,16)</sup>

Yates compared the response of injections of anesthetics to injections of anesthetics combined with steroids and found better outcomes in the latter group.<sup>(17)</sup> Combinations of the various constituents applied epidurally are also being adopted as tools in the surgeon's armamentarium to enhance successful treatment of postoperative pain in lumbar surgery.<sup>(3,5,6,12,14)</sup> Because so many solutions are available for the same surgical problem, it is our belief that the gold standard is still far from being selected. The most difficult challenge posed by sustained-released regimens is maintaining a low concentration in cerebral-spinal fluid (CSF) and decreasing the infection rate. To address these issues, some authors have pointed out theoretical reasons why complication rates or failure rates of those with previous surgeries may be so high.<sup>(16,18,19)</sup> Despite these arguments for and against the use of epidural sustained-released regimens, increasing experimental work has been reported to support either method for pain control after lumbar surgery, as well as the use of this compound as opposed to an epidural catheter to reduce infection morbidity.<sup>(6,17,20,21)</sup> Opiate drugs are known to exert only not a direct anti-nociceptive influence on the spinal cord, but also a direct endogenous inhibitory effect according to the drug's concentration in the CSF. The pharmacokinetics of epidurally administered narcotics appears to be due to passage of these agents across the dura, where it acts on opiate receptors both in the spinal cord and in the supraspinal structure.<sup>(15,20,22)</sup> Epidural steroids may effectively decrease the inflammation reaction induced by tissue damage and surgical manipulation.<sup>(14,18)</sup> Our review shows that lowering the dose of epidural steroids (as in group B) may reduce the infection rate and achieve similar pain control as does a higher steroid dose. Using this compound, binding of the drug at low spinal levels and the slow



rostral circulation of cerebrospinal fluid may limit respiratory depression with epidural administration of narcotics. Postoperative infiltration of surgical wounds with 0.25% bupivacaine may theoretically result in significant reduction in pain, both at rest and during mobilization.<sup>(14,22,23)</sup> However, considering the time of using opioid analgesics, early consumption of narcotics (less than 8 hours) was seen in 58 postoperative patients (72.5%), and the rate would increase to 85.7% if only the 63 patients who needed the narcotics were assessed. We were unable to demonstrate the benefits of paravertebral wound infiltration with bupivacaine in the present study. The value of high-dose local anesthesia in this situation may be questioned.

The adverse effects of morphine, subcutaneous fluid collection and foreign epidural masses from blood and solvents are always a problem and limit the effects of sustained-released agents. The prolonged necessity for narcotics consumption in deeply infected patients attracted our early attention to the complicated adverse events. Of the 4 patients with complications of deep infections, only one had a history of renal disease, and there seems to be no contraindication of this application for patients associated with preoperative major health problems. Three patients who suffered from deep infections, however, had histories of herbal drug/acupuncture treatment (3 in 22 patients), compared to 1 in 58 patients who had no experience with herbal drug/acupuncture treatment. Although the frequency of use of herbal drugs or acupuncture in our patients may predispose a patient to infection in our analysis, no conclusion can be made from this data due to the unknown constituents of the herbal drugs. After excluding the possibility that general anesthesia was the cause, the postoperative convulsions seen in 1 patient may be attributable to an allergic reaction to bupivacaine, a devastating response to this local anesthetic.<sup>(23)</sup> Cost is a significant concern in today's medical environment, and patients undergoing the pain control procedure may significantly reduce the need for narcotics consumption and their length of stay.

Although the study is limited by the use of well-designed comparative clinical groups rather than a double-blind placebo-controlled group, this study may be the first such review in our country, and the results must be considered preliminary. Sensory or

motor loss, urinary retention, or itching did appear in some patients after epidural morphine, but the side effects were minor and appeared to fade within a few hours to 3 days. When recovery time and surgical morbidity are both decreased, an epidural pain regimen can be considered extremely effective.

Careful patient selection, decreasing the dose of methylprednisolone and adjusting bupivacaine may be more likely to decrease the major adverse effects of pain-control therapy. Based on these findings, we believe that total pain relief and safety in lumbar decompressive surgery can be obtained with relatively low doses of morphine and methylprednisolone soaked in epidural microfibrillary collagen. Despite the clinical attractiveness, it has yet to be proven whether this method should be advocated in instrumentation surgery or cervical procedures.

#### Acknowledgments

The author would like to thank Ms. Shu Yun for assistance with the preparation of the manuscript and Ms. Chen Fu Ru for help with statistical analysis.

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# 腰椎椎板移除術中以硬腦膜上類固醇及嗎啡溶入微纖維膠原蛋白 以達術後止痛效果：初步報告

陳子勇

**背景：**現今於腰椎手術後之住院病患是以肌肉注射麻藥、非類固醇止痛劑或自控式點滴嗎啡等方法來達到傷口止痛的作用，但各種方法都有其限制和缺點。

**方法：**以非隨機且前瞻性的方法，將80位病患分成不同類固醇劑量的兩組，記載和統計病患的疼痛指數、麻藥使用劑量、住院時間、術後行走能力及併發症等。

**結果：**腰椎手術之後的傷口疼痛可以被有效的控制，75位病患(97.5%)可於術後第一天下床自行行走。主要的併發症發生於5位病患(6.2%)。

**結論：**使用硬腦膜上止痛藥粉於腰椎椎板移除術，可有效的控制術後的傷口疼痛。早期活動，有經濟效益和減少止痛藥的使用。低劑量的甲基類固醇除可減少併發症外同時可達到良好的止痛效果。臨床上使用時仍應注意由止痛藥及藥粉引起的併發症。

(長庚醫誌 2002;25:81-8)

**關鍵字：**硬腦膜上嗎啡，甲基皮質類醇，椎板移除術，痛。